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Medacta International

510(k) Summary

FEB 13 2008

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Date Prepared: February 4, 2008

DEVICE INFORMATION

Trade/Proprietary Name: MectaCer BIOLOX® *forte* Femoral Heads
Common/Classification Name: Hip Joint, metal/ceramic/polymer, semi-constrained, cemented or non-porous uncemented prosthesis
21 CFR 888.3353
Class II
Device Product Code: LZO

Predicate Devices:
The MectaCer BIOLOX® *forte* Femoral Heads are substantially equivalent to Plus Ceramic Ball Heads 28, 32 & 36, which were cleared under K070928 and Exactach® 12/14 Alumina Femoral Heads, which were cleared under K032964.

Product Description:
The MectaCer BIOLOX® *forte* Femoral Heads are ceramic ball heads intended for mechanical fixation to a mating hip stem and indicated for the treatment of patients who are candidates for total or partial hip arthroplasty to provide

increased patient mobility and reduced pain by replacing the damaged hip joint, in primary or revision surgery.

The MectaCer BIOLOX® *forte* Femoral Heads consist of High Purity Aluminium Oxyde Ceramic, Al_2O_3, per standard ISO 6474:1994, Implants for surgery – Ceramics materials based on high purity alumina, Type A. The MectaCer BIOLOX® *forte* Femoral Heads are available in various sizes from 28, 32 and up to 36 mm diameters.

Indications for Use:
The MectaCer BIOLOX® *forte* Femoral Heads are intended for mechanical fixation to a mating hip stem and indicated for treatment of patients who are candidates for total or partial hip arthroplasty in primary or revision surgery.
The patient should be skeletally mature.
The patient's condition should be due to one or more of the following:

- Severely painful and/or disabled joint as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or psoriatic arthritis.
- Congenital hip dysplasia
- Ankylosing spondylitis
- Avascular necrosis of the femoral head
- Acute traumatic fracture of the femoral head or neck
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement where sufficient bone stock is present.

Performance Testing
No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the MectaCer BIOLOX® *forte* Femoral Heads was conducted in accordance with the following international standards and FDA guidance documents.

- ISO 6474:1994, Implants for surgery – Ceramic materials based on high purity alumina
- ISO 7206-10, 2003, Implants for surgery – Partial and total hip-joint prosthesis – Part 10: Determination of resistance to static load of modular femoral heads.
- ASTM F-2009-00, Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses
- AAMI/ANSI/ISO 11137 Sterilization of health care products – Radiation
- FDA's "Guidance Documents for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems", January 10, 1995.

Conclusion:
The data and information provided in this submission support the conclusion that the MectaCer BIOLOX® *forte* Femoral Heads are substantially equivalent to its

predicate devices, Plus Ceramic Ball Heads 28, 32 & 36, and Exactech® 12/14 Alumina Femoral Heads with respect to indications for use and technological characteristics. Actual device performance as tested conforms to applicable standards and FDA guidance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2008

MEDACTA International SA
% Ms. Natalie J. Kennel
NJK & Associates, Incorporated
13721 Via Tres Vista
San Diego, California 92129

Re: K073337
Trade/Device Name: MectaCer BIOLOX® *forte* Femoral Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Regulatory Class: Class II
Product Code: LZO
Dated: November 27, 2007
Received: November 29, 2007

Dear Ms. Kennel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073337

Device Name: MectaCer BIOLOX® *forte* Femoral Heads

Indications for Use:

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- Acute traumatic fracture of the femoral head or neck
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement where sufficient bone stock is present.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073337